DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

June 6, 2001

WARNING LETTER NO. 2001-NOL-28

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Allen J. Dugas, Owner
Louisiana Seafood Company
1865 Coteau Holmes Highway
St. Martinville, Louisiana 70582

Dear Mr. Dugas:

We inspected your firm, located at 1865 Coteau Holmes Highway, St. Martinville, Louisiana, on May 9, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your vacuum-packed crawfish product to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures during the packing or cooler storage critical control points to control pathogen growth as listed in your HACCP plan for your vacuum-packed crawfish product. These deviations were previously brought to your attention in our letter of August 10, 1999.

- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not perform the following:

    1. Your firm did not document monitoring sanitation conditions for 12 of 14 days of processing;

    2. Your firm did not monitor for the prevention of cross-contamination from insanitary objects to food with sufficient frequency, as employees routinely handled unsanitized objects then cooked product without sanitizing their hands; and,

3. Your firm did not monitor for the protection of food packaging materials from condensation. Condensation dripped from an air-condition unit directly into a sink used to wash, sanitize, and rinse the finished product containers.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of temperature monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR, Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Carl E. Draper

Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483